AMENDMENTS TO THE CLAIMS

Applicants have submitted a new complete claim set showing marked up claims with insertions indicated by underlining and deletions indicated by strikethroughs and/or double bracketing.

Please add new claims 112-114 as noted below. No new matter has been added.

Support for the claims can be found on page 16, line 31 of the instant specification.

1. (original) A method for treating irritable bowel syndrome comprising administering to a patient in need of such treatment an amount of a pharmaceutical preparation comprising a peripheral opioid antagonist effective to ameliorate at least one symptom of the irritable bowel syndrome, wherein the pharmaceutical preparation is free of bioavailable calcium or salts thereof.

2. (original) The method of claim 1 wherein the pharmaceutical preparation is administered parenterally.

3. (original) The method of claim 2 wherein the pharmaceutical preparation is administered from a route selected from the group consisting of intravenously, subcutaneously, via a needleless injection, and via infusion.

4. (original) The method of claim 3 wherein the pharmaceutical preparation is administered intravenously.

5. (original) The method of claim 3 wherein the pharmaceutical preparation is administered subcutaneously.

6. (original) The method of claim 3 wherein the pharmaceutical preparation is administered via a needleless injection.

7. (original) The method of claim 3 wherein the pharmaceutical preparation is administered via an infusion.

8. (original) The method of claim 1 wherein the pharmaceutical preparation is administered intrarectally.

9. (original) The method of claim 1 wherein the pharmaceutical preparation is administered transdermally.

10. (original) The method of claim 1 wherein the pharmaceutical preparation is administered intranasally.

11. (original) The method of claim 1 wherein the pharmaceutical preparation is administered as a solution.

12. (original) The method of claim 1 wherein the pharmaceutical preparation is administered as a suppository.

13. (original) The method of claim 1 wherein the pharmaceutical preparation is administered as an enema.

14. (original) The method of claim 1 wherein the pharmaceutical preparation is administered as a tablet or capsule.

15. (original) The method of claim 1 wherein the patient is not undergoing exogenous opioid treatment.

16. (original) The method of claim 1 wherein the patient is female.

17. (original) The method of claim 1 wherein the patient is male.

18. (original) The method of claim 1 wherein the patient is a child.

19. (original) The method of claim 1 wherein the symptom is diarrhea.

20. (original) The method of claim 1 wherein the symptom is alternating constipation and diarrhea.

21. (original) The method of claim 1 wherein the symptom is constipation.

22. (original) The method of claim 1 wherein the symptom is constipation and abdominal pain.

23. (original) The method of claim 1 wherein the symptom is abdominal bloating.

24. (original) The method of claim 1 wherein the symptom is abdominal distension.

25. (original) The method of claim 1 wherein the symptom is abnormal stool frequency.

26. (original) The method of claim 1 wherein the symptom is abnormal stool consistency.

27. (original) The method of claim 1 wherein the symptom is abdominal pain.

28. (original) The method of claim 1 further comprising administering an antibiotic to the patient.

29. (original) The method of claim 1 further comprising administering an opioid agonist to the patient.

30. (original) The method of claim 1 further comprising administering at least one irritable bowel syndrome therapeutic agent to the patient.

31. (original) The method of claim 30, further comprising administering an opioid agonist to the patient.

32. (original) The method of claim 30, wherein the irritable bowel syndrome therapeutic agent is selected from the group consisting of antispasmodics, anti-muscarinics, antiinflammatory agents, pro-motility agents, $5HT_1$ agonists, $5HT_3$ antagonists, $5HT_4$ antagonists, $5HT_4$ agonists, bile salt sequestering agents, bulk-forming agents, alpha2-adrenergic agonists, mineral oils, antidepressants, herbal medicines, and combinations thereof.

33. (original) The method of claim 30, wherein the irritable bowel syndrome agent is not a $5HT_3$ antagonist, a $5HT_4$ antagonist, or a $5HT_4$ agonist.

34. (original) The method of claim 30 wherein the irritable bowel syndrome therapeutic agent is an antidiarrheal medication.

35. (original) The method of claim 30 wherein the irritable bowel syndrome therapeutic agent is an antidepressant.

36. (original) The method of claim 30 wherein the irritable bowel syndrome therapeutic agent is an herbal medicine.

37. (original) The method of claim 30 wherein the irritable bowel syndrome therapeutic agent is an $alpha_2$-adrenergic agent.

38. (original) The method of claim 30 wherein the agent is a $5HT_4$ agonist.

39. (original) The method of claim 38, wherein the $5HT_4$ agonist is 3-(5-methoxy-IM-indole-3-yl-methylene)-N-pentylcarbazimidamide.

40. (original) The method of claim 30 wherein the agent is polyethylene glycol 3350.

41. (previously presented) The method of claim 1 wherein the peripheral opioid antagonist is a quaternary derivative of noroxymorphone.

42. (original) The method of claim 41 wherein the quaternary derivative of noroxymorphone is methylnaltrexone.

43. (original) The method of claim 41 wherein the amount of the quaternary derivative of noroxymorphone ranges from 1.0 to 3.0 mg/kg.

44. (original) The method of claim 43 wherein the quaternary derivative of noroxymorphone is methylnaltrexone.

45. (original) The method of claim 41 wherein the amount of the peripheral opioid antagonist ranges from 0.1 to 0.45 mg/kg.

46. (original) The method of claim 42 wherein the amount of the quaternary derivative of noroxymorphone ranges from 0.1 to 0.45 mg/kg.

47. (original) The method of claim 3 wherein the pharmaceutical preparation is administered by infusion.

48. (previously presented) The method of claim 40 wherein the amount of peripheral opioid antagonist is effective to achieve a mean peak plasma concentration of 1400 ng/ml or less of peripheral opioid antagonist.

49. (original) The method of claim 48 wherein the mean peak plasma concentration is 1200 ng/ml or less of peripheral opioid antagonist.

50. (original) The method of claim 48 wherein the mean peak plasma concentration is 1000 ng/ml or less of peripheral opioid antagonist.

51. (original) A method for treating irritable bowel syndrome comprising orally administering to a patient in need of such treatment an amount of a pharmaceutical preparation comprising a peripheral opioid antagonist effective to ameliorate at least one symptom of the irritable bowel syndrome, wherein the pharmaceutical preparation is free of bioavailable calcium or salts thereof.

52. (original) The method of any one of claim 51 wherein the pharmaceutical preparation is administered in an enteric coated formulation.

53. (original) The method of any one of claim 51 wherein the pharmaceutical preparation is administered in a sustained release formulation.

54. (original) The method of any one of claim 51 wherein the pharmaceutical preparation is administered in an enteric coated sustained release formulation.

55. (original) The method of any of one claim 51 wherein the pharmaceutical preparation is administered in a colonic site-directed formulation.

56. (original) The method of claim 51 wherein the patient is not undergoing exogenous opioid treatment.

57. (original) The method of claim 51 wherein the patient is female.

58. (original) The method of claim 51 wherein the patient is male.

59. (original) The method of claim 51 wherein the patient is a child.

60. (original) The method of claim 51 wherein the symptom is constipation.

61. (original) The method of claim 51 wherein the symptom is constipation and abdominal pain.

62. (original) The method of claim 51 wherein the symptom is diarrhea.

63. (original) The method of claim 51 wherein the symptom is alternating constipation and diarrhea.

64. (original) The method of claim 51 wherein the symptom is abdominal bloating.

65. (original) The method of claim 51 wherein the symptom is abdominal distension.

66. (original) The method of claim 51 wherein the symptom is abnormal stool frequency.

67. (original) The method of claim 51 wherein the symptom is abnormal stool consistency.

68. (original) The method of claim 51 wherein the symptom is abdominal pain.

69. (original) The method of claim 51 further comprising administering an antibiotic to the patient.

70. (original) The method of claim 51 further comprising administering at least one irritable bowel syndrome therapeutic agent.

71. (original) The method of claim 70 wherein the irritable bowel syndrome therapeutic agent is an antidepressant.

72. (original) The method of claim 70 wherein the irritable bowel syndrome therapeutic agent is an antidiarrheal medication.

73. (original) The method of claim 70 wherein the irritable bowel syndrome therapeutic agent is an herbal medicine.

74. (original) The method of claim 70 wherein the irritable bowel syndrome therapeutic agent is an opioid agonist.

75. (original) The method of claim 70 wherein the irritable bowel syndrome therapeutic agent is an $alpha_2$-adrenergic agent.

76. (original) The method of claim 70 wherein the irritable bowel syndrome therapeutic agent is a 5-HT_4 agonist.

77. (original) The method of claim 65 wherein the 5-HT_4 agonist is 3-(5-methoxy-IM-indole-3-yl-methylene)-N-pentylcarbazimidamide.

78. (original) The method of claim 70 wherein the irritable bowel syndrome therapeutic agent is not a 5-HT_3 antagonist, a 5-HT_4 antagonist or a 5-HT_4 agonist.

79. (original) The method of claim 76 wherein the irritable bowel syndrome therapeutic agent is a polyethylene glycol 3350.

80. (previously presented) The method of claim 51 wherein the peripheral opioid antagonist is a quaternary derivative of noroxymorphone.

81. (original) The method of claim 80 wherein the quaternary derivative of noroxymorphone is methylnaltrexone.

82. (original) The method of claim 81 wherein the amount ranges from 50 to 750 mg/day.

83. (original) The method of claim 81 wherein the amount is 75 mg of the quaternary derivative of noroxymorphone.

84. (original) The method of claim 81 wherein the amount is 225 mg of the quaternary derivative of noroxymorphone.

85. (original) A pharmaceutical preparation comprising a quaternary derivative of noroxymorphone and an irritable bowel syndrome therapeutic agent and a pharmaceutically acceptable carrier.

86. (original) The pharmaceutical preparation of claim 85 wherein the quaternary derivative of noroxymorphone is methylnaltrexone.

87. (original) The pharmaceutical preparation of claim 85 or 86 wherein the pharmaceutical preparation is free of bioavailable calcium or salts thereof.

88. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is selected from the group consisting of antispasmodics, anti-muscarinics, antiinflammatory agents, pro-motility agents, $5HT_1$ agonists, $5HT_3$ antagonists, $5HT_4$ antagonists, $5HT_4$ agonists, bile salt sequestering agents, bulk-forming agents, $alpha_2$-adrenergic agonists, mineral oils, antidepressants, herbal medicines and combinations thereof.

89. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is an antispasmodic.

90. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is an anti-muscarinic.

91. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is an antiinflammatory agent.

92. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is a pro-motility agent.

93. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is a $5HT_1$ agonist, a $5HT_3$ antagonist or a $5HT_4$ agonist.

94. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is not a $5HT_3$ antagonist, a $5HT_4$ antagonist or a $5HT_4$ agonist.

95. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is a $5HT_4$ agonist.

96. (original) The pharmaceutical preparation of claim 95 wherein the irritable bowel syndrome therapeutic agent is 3-(5-methoxy-IM-indole-3-yl-methylene)-N-pentylcarbazimidamide.

97. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is a bile salt sequestering agent.

98. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is a bulk-forming agent.

99. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is an alpha2-adrenergic agonist.

100. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is a mineral oil.

101. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is an antidepressant.

102. (original) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is an herbal medicine.

103. (previously presented) The pharmaceutical preparation of claim 85 wherein the pharmaceutical preparation is formulated for oral administration.

104. (original) The pharmaceutical preparation of claim 102 wherein the formulation is selected from the group consisting of a capsule, a powder, a granule, a crystal, a tablet, a solution, an extract, a suspension, a soup, a syrup, an elixir, a tea, a liquid-filled capsule, an oil, a chewable tablet, a chewable piece, an enteric-coated tablet, a sustained release tablet or capsule, and an enteric-coated sustained release tablet.

105. (previously presented) The pharmaceutical preparation of claim 85 wherein the pharmaceutical preparation is formulated for rectal administration.

106. (original) The pharmaceutical preparation of claim 105 wherein the formulation is selected from the group consisting of a suspension, a solution, a suppository, an oil, and an enema.

107. (previously presented) The pharmaceutical preparation of claim 85 wherein the pharmaceutical preparation is formulated for a route of administration selected from the group consisting of sublingual, intranasal, transdermal, intradermal, intramuscular, subcutaneous, injectable, and infusion.

108. (original) A kit comprising:

a package containing a peripheral opioid antagonist preparation, wherein the preparation is free of bioavailable calcium and salts thereof; and

instructions for using the preparation to treat irritable bowel syndrome.

109. (original) The kit of claim 108, further comprising an antibiotic.

110. (original) The kit of claim 108, further comprising an irritable bowel syndrome therapeutic agent

111. (previously presented) The kit of claim 108, wherein the preparation is a pharmaceutical preparation according to claim 85.

112. (new) The method of claim 38 wherein the $5HT_4$ agonist is tegaserod maleate.

113. (new) The method of claim 76 wherein the $5HT_4$ agonist is tegaserod maleate.

114. (new) The pharmaceutical preparation of claim 95 wherein the irritable bowel syndrome therapeutic agent is tegaserod maleate.

RESPONSE TO ELECTION OF SPECIES REQUIREMENT

In response to the election requirement, applicant hereby elects the following species covered by claims 1 and 108, specifically, methylnaltrexone as a species of peripheral opioid antagonist, tegaserod maleate (chemical name 3-(5-methoxy-1H-indol-3-ylmethylene)-N-pentylcarbazimidamide hydrogen maleate) as a species of irritable bowel syndrome therapeutic agent and oral administration as one method of administration. New claims 112-114 have been added which recite the elected species. Support for the claims can be found on page 16, line 31 of the instant specification.

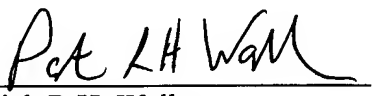
Applicant's election is made without prejudice. As noted by the Examiner, upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to not more than a reasonable number of species in addition to the elected species, provided that all claims to each additional species are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.146.

For clarification, the present claims are directed to methods, compositions and kits for treating irritable bowel syndrome, not respiratory conditions as stated by the Examiner on page 4 of the Office Action.

An action on the merits of all the claims and a Notice of Allowance thereof are respectfully requested.

Dated: July 25, 2006

Respectfully submitted,

By 

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